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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | | 10823691 | |
| | Filing Date | | 2004-04-14 | |
| | First Named Inventor | SOLDIN, Steven J. | | |
| | Art Unit | 1645 | | |
| | Examiner Name | | | |
| Attorney Docket Number | | 31603-2053 | | |

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| 1 | KISSMEYER ET AL., Determination of the vitamin D analog EB 1089 (seocalcitol) in human and pig serum using liquid chromatography-tandem mass spectrometry, Journal of Chromatography. Biomedical Applications, Elsevier, Amsterdam, NL. vol 740. no. 1, March 2000, 117-128 | <input type="checkbox"/> |
| 2 | JONSSON ET AL., Determination of cortisol in human saliva using liquid chromatography-electrospray tandem mass spectrometry, Journal of Chromatography B: Biomedical Sciences & Applications, Elsevier Science Publishers, NL, vol. 784, no. 1, January 2003, 63-68 | <input type="checkbox"/> |
| 3 | FREDLINE ET AL., A reference method for the analysis of aldosterone in blood by high-performance liquid chromatography-atmospheric pressure chemical ionization-tandem mass spectrometry, Analytical Biochemistry, vol. 252, no. 2, 1997, 308-313 | <input type="checkbox"/> |
| 4 | LEINONEN ET AL., Liquid chromatography/mass spectrometry in anabolic steroid analysis: optimization and comparison of three ionization techniques: electrospray ionization, atmospheric pressure chemical ionization and atmospheric pressure photoionization, Journal of Mass Spectrometry, vol. 37, no. 7, July 2002, 693-698 | <input type="checkbox"/> |
| 5 | VOGESER ET AL., Determination of serum cortisol by isotope-dilution liquid-chromatography electrospray ionization tandem mass spectrometry with on-line extraction, Clinical Chemistry and Laboratory Medicine, vol. 39, no. 10, October 2001, 944-947 | <input type="checkbox"/> |
| 6 | ROBB ET AL., Atmospheric pressure photoionization: An ionization method for liquid chromatography - Mass spectrometry, Analytical Chemistry, August 2000, United States, vol. 72, no. 15, 3653-3659 | <input type="checkbox"/> |
| 7 | Analyze additional compound classes with the PhotoSpray™ atmospheric pressure photoionization source, Product Bulletin, Applied Biosystems, MDS Sciex, Online! 2002 | <input type="checkbox"/> |
| 8 | CHOI ET AL., Rapid HPLC-Electrospray Tandem Mass Spectrometric Assay for Urinary Testosterone and Dihydrotestosterone Glucuronides from Patients with Benign Prostate Hyperplasia, Clinical Chemistry, vol. 49, no.2, 2003, 322-325 | <input type="checkbox"/> |
| 9 | BIANCOTTO ET AL., Determination of 17 β -estradiol in bovine plasma: development of a highly sensitive technique by ion trap gas chromatography-tandem mass spectrometry using negative chemical ionization +, Journal of Mass Spectrometry, 2002, vol. 37, 1266-1271 | <input type="checkbox"/> |
| 10 | LAI, ET AL., Rapid Screening Assay of Congenital Adrenal Hyperplasia by Measuring 17 α -Hydroxyprogesterone with High-Performance Liquid Chromatography/Electrospray Ionization Tandem Mass Spectrometry from Dried Blood Spots, Journal of Clinical Laboratory Analysis, vol. 16, 2002, 20-25 | <input type="checkbox"/> |
| 11 | VIERHAPPER ET AL., Reduced Production Rates of Testosterone and Dihydrotestosterone in Healthy Men Treated with Rosiglitazone, Metabolism, vol. 52, no. 2, February 2003, 230-232 | <input type="checkbox"/> |

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| | 12 | ALARY ET AL., Comparative Study: LC-MS/MS Analysis of Four Steroid Compounds Using a New Photoionization Source and a Conventional APCI Source, Proceedings of the 49th ASMS Conference on Mass Spectrometry and Allied Topics, Chicago, Illinois, May 27-31, 2001 | <input type="checkbox"/> |
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

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| Signature | | Date (YYYY-MM-DD) | |
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|------------------------|---|-------------------|------|
| In re Application of | SOLDIN, Steven J. | | |
| Serial No.: | 10/823,691 | | |
| Filing or 371(c) Date: | 04/14/2004 | | |
| Title: | STEROID HORMONE ANALYSIS BY MASS SPECTROMETRY | | |
| Art Unit: | 1645 | | |
| Atty's Docket No.: | 31603-2053 | Confirmation No.: | 5360 |
| Customer No.: | 33721 | | |

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INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 AND 1.98

Dear Sir:

Applicant submits herewith patents, publications, and other information of which Applicant is aware, and which Applicant believes may be material, as defined in 37 CFR §1.56(b), to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 CFR §1.56(b), the filing of this Information Disclosure Statement is not intended to, pursuant to 37 CFR §1.97(h), constitute an admission that any patent, publication, or other information referred to is, or is considered to be, material to the patentability of this invention. No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103, and Applicant reserves the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish otherwise. Further, pursuant to 37 CFR §1.97(g), the filing of this Statement should not be construed as a statement that a search has been made or that no other material information exists.

The Office has waived the requirement pursuant to 37 CFR §1.98(a)(2)(i) for submitting a copy of each cited US patent and each US patent application publication for all US national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC §371 after June 30, 2003. Therefore, no copies of each cited US patent are enclosed, but the cited US patents are listed on the attached PTO/SB/08a.

Any telephone call regarding this submission should be made to the undersigned at (416) 865-8242.

Yours very truly,



Matthew J. Marquardt
Registration No. 40997

November 30, 2006
Date

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